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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,273	03/31/2004	Akira Ito	F-8198	7488

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,273	ITO ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,11,14,35-37 and 41-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5,11,14,35,36 and 41-45* is/are allowed.

6)☒ Claim(s) *37 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed September 25, 2006 in response to the Office Action of June 20, 2006, is acknowledged and has been entered. Previously pending claims 5, 11, 14, 35,36, 37 have been amended. New claims 41-46 have been added. Claims 4, 6, 8, 9, 12, 19, 20, 23, 33, 34, and 38-40 were canceled.

Examiner rejoins claim 37 for prosecution because arguments are persuasive.

Claims 5, 11, 14, 35-37, and 41-46 are currently being examined.

NEW REJECTIONS

(based on new considerations)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 37 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "**magnetic fine particles comprise an antibody**". It is unclear how magnetic fine particles can "comprise" an antibody.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 37 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to the hyperthermia method according to claim 41 or 42 wherein said magnetic fine particles comprise an antibody which selectively binds to malignant tumor cells.

The specification discloses that "the magnetic fine particles preferably used in the present invention, there may be mentioned magnetic fine particles on the surface of which is bound an antibody that selectively binds to the malignant tumor cells. The magnetic fine particles to which an antibody is bound are selectively concentrated at the neighbor of the malignant tumor cells, so that hyperthermia can be carried out without heating cells other than the malignant tumor cells" (p. 6, lines 5-12), and "the magnetic fine particles to which an antibody which selectively binds to the malignant tumor cells is bound on the surface thereof to be used in the present invention can be produced by, for example, the method disclosed in Japanese Provisional Patent Publication No. Hei. 3-128331, that is, by binding a bifunctional cross-linking agent to the magnetic fine particles, and then, an antibody which selectively binds to the malignant tumor cells is reacted therewith" (p.8, lines 4-12). Original claim 3 recited "the hyperthermia method according to claim 1 or 2 wherein magnetic fine particles are magnetic fine particles on the surface of which is bound to an antibody which selectively binds to malignant tumor cells".

One cannot extrapolate the disclosure of the specification to the enablement of the claims because one of ordinary skill in the art understands that magnetic fine particles cannot physically "comprise and antibody". However, the art teaches that magnetic fine particles can be coated or wrapped in a liposome and antibodies can be

covalently linked to the liposomal surface. This strategy is reviewed by Ito et al (J of Bioscience and Bioengineering, 2005, 100:1-11), see pages 4-5, Figure 4A. Because the method of claims 41 or 42 do not include liposome coatings on the magnetic fine particles, one of skill in the art would not know how to link the antibody to the magnetic fine particle or how to make a magnetic fine particle "comprise" an antibody.

Therefore, in view of the state of the art, the lack of guidance in the specification, and the absence of working examples, and the relative skill of those in the art, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

4. **Conclusion:** Claims 5, 11, 14, 35-36, and 41-45 are allowable. The claims have been narrowed in scope to a method of treating a malignant tumor comprising administering a cytokine, IL-2 or GMCSF, to a malignant tumor, subjecting the tumor to hyperthermia and comprising administering magnetic fine particles to said tumor and heating said fine particles, wherein the fine particles are magnetite, ferrite, or permalloy. The limitations to cytokines IL-2 or GMCSF overcome the 103(a) prior art rejection under Ito et al (see section 5 of the previous Office Action) because Ito et al does not specifically teach or suggest using IL-2 or GMCSF in the hyperthermia method. Applicants also submitted a declaration stating the snynergistic effects of the claimed hyperthermia method with cytokines IL-2 or GMCSF as compared to treatment with either agent alone (declaration mailed 4/6/2006).

Claims 37 and 46 are rejected under 35 U.S.C. 112, first paragraph.

5. All other rejections recited in the Office Action mailed June 20, 2006 are hereby withdrawn.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SHANON A. FOLEY
SUPERVISORY PATENT EXAMINER